

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 38

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte YANN MAHE and BRUNO BUAN

Appeal No. 2001-1836
Application No. 08/716,531

HEARD: July 9, 2002

MAILED

AUG 15 2002

**PAT. & TM. OFFICE
BOARD OF PATENT APPEALS
WASHINGTON, DC**

Before WINTERS, SCHEINER, and ADAMS, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

This appeal was taken from the examiner's decision rejecting claims 1 through 11 and 16 through 19, which are all of the claims remaining in the application.

REPRESENTATIVE CLAIMS

Claims 1 and 3, which are illustrative of the subject matter on appeal, read as follows:

1. A method of treating inflammation comprising administering a therapeutically effective amount of a pharmaceutical/cosmetic composition of matter, comprising an anti-inflammatory effective amount of at least one peptide comprising the lysine-proline-

valine tripeptide sequence, the proline moiety of which exists in its dextrorotatory optical isomer form (DPro), wherein said peptide comprises anti-inflammatory activity, in a physiologically/pharmaceutically acceptable medium therefor, and where the lysine and valine residues contained in said lysine-proline-valine tripeptide sequence exist either in their levorotatory of [sic] dextrorotary forms.

3. The method as defined in Claim 1, said at least one peptide comprising the lysine-proline-valine tripeptide, the proline moiety of which exists in its dextrorotary optical isomer form (DPro).

THE PRIOR ART REFERENCES

In rejecting the appealed claims on prior art grounds, the examiner relies on the following references:

Ferreira et al (Ferreira)	5,389,615	Feb. 14, 1995
Lipton	5,157,023	Oct. 20, 1992
Nordlund et al. (Nordlund)	4,874,744	Oct. 17, 1989

Oluyomi et al. (Oluyomi), "Antinociceptive activity of peptides related to interleukin-1beta-(193-195), Lys-Pro-Thr," European Journal of Pharmacology, Vol. 258, pp. 131-38, (1994).

Mullins, "Medicated Applications," Remington's Pharmaceutical Sciences, Chapter 87, pp. 1518-1534 (16th ed., Pennsylvania, Mack Publishing Co., 1980).

Sciarra, "Aerosols," Remington's Pharmaceutical Sciences, Chapter 92, pp. 1614-1628 (16th ed., Pennsylvania, Mack Publishing Co., 1980).

THE REJECTIONS

The appealed claims stand rejected as follows:

- (1) Claims 1 through 3 under 35 U.S.C. § 102(b) as described by Ferreira or Oluyomi;

- (2) Claims 4, 7 through 10, and 18 under 35 U.S.C. § 103(a) as unpatentable over Ferreira;
- (3) Claims 5, 6, and 19 under 35 U.S.C. § 103(a) as unpatentable over the combined disclosures of Ferreira, Lipton, and Oluyomi;
- (4) Claims 1 through 11 and 16 through 19 under 35 U.S.C. § 103(a) as unpatentable over the combined disclosures of Ferreira, Nordlund, Lipton, Oluyomi, and Remington's Pharmaceutical Sciences (Chapters 87 and 92); and
- (5) Claims 1 through 3, 5 through 11, and 16 through 19 under 35 U.S.C. § 103(a) as unpatentable over the combined disclosures of Oluyomi, Nordlund, Lipton, and Remington's Pharmaceutical Sciences (Chapters 87 and 92).

DELIBERATIONS

Our deliberations in this matter have included evaluation and review of the following materials:

- (1) The instant specification, including claims 1 through 11 and 16 through 19;
- (2) Applicants' Brief (Paper No. 31) and the Reply Brief (Paper No. 34);
- (3) The Examiner's Answer (Paper No. 32);
- (4) The above-cited prior art references;
- (5) The Mahe Declaration, filed under the provisions of 37 CFR § 1.132, executed July 20, 1998;

- (6) The Hoffmann and Schmelz abstract of an article appearing in Eur. J. Pain 1999 Jun., 3(2): 131-39 entitled "Time course of UVA- and UVB- induced inflammation and hyperalgesia in human skin."; and
- (7) Pages 281 through 283 and 292 from the textbook "Drugs Used To Suppress Inflammatory And Immune Reactions" attached to Paper No. 8 received in the administrative file January 15, 1998.

On consideration of the record, including the above-listed materials, we reverse the examiner's rejections under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a).

THE EXAMINER'S REJECTIONS

We agree with the examiner's finding that Ferreira and Oluyomi constitute relevant prior art. These references disclose the tripeptide lysine-D-proline-valine, recited in claims 1 through 11 and 16 through 19. These references also disclose that lysine-D-proline-valine possesses analgesic activity, and may be used in a method of treating or alleviating pain.

Treating pain, however, is not equivalent with or identical to treating inflammation. As stated in paragraph (12) of the Mahe Declaration, filed under the provisions of 37 CFR § 1.132, it cannot be reasonably extrapolated that a compound which alleviates pain, i.e., an analgesic, will necessarily also inhibit inflammation. Some compounds, e.g., some of the commonly used non-steroidal anti-inflammatory drugs, have both analgesic and anti-inflammatory properties. Others, however, have analgesic but not anti-inflammatory activity. For example, during prosecution, applicants referred to a textbook discussion, "Drugs Used To Suppress Inflammatory And Immune Reactions"

(attached to Paper No. 8, received January 15, 1998), disclosing that the therapeutic agent Paracetamol has analgesic and antipyretic properties; but does not have anti-inflammatory activity.

On this record, the examiner has not established that either Ferreira or Oluyomi describes or suggests a method of treating inflammation recited in the appealed claims. Nor do the remaining references shore-up the deficiencies of Ferreira or Oluyomi. Accordingly, we are constrained to reverse each of the examiner's rejections under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a).

OTHER ISSUES

1. Claim 3

On return of this application to the examining corps, we recommend that the examiner reevaluate whether claim 3 constitutes a proper dependent claim. It appears to this merits panel that claim 3 is improper because it does not add a further limitation to the method of treating inflammation recited in claim 1. See 35 U.S.C. § 112, fourth paragraph. That is, claim 3 simply reiterates the limitation in claim 1 requiring "at least one peptide comprising the lysine-proline-valine tripeptide, the proline moiety of which exists in its dextrorotatory optical isomer form (DPro)." At oral argument on July 9, 2002, counsel for applicants, in response to questioning by the panel, agreed that dependent claim 3 does not appear to further limit claim 1.¹

¹ Barbara Walker (Reg. No. 35,400) represented applicants at the hearing on July 9, 2002.

2. The Hiltz Reference

On return of this application to the examining corps, we recommend that the examiner reevaluate the patentability of all the appealed claims over Hiltz.²

In our judgment, Hiltz constitutes the closest prior art of record. This reference clearly and unequivocally describes a lysine-proline-valine tripeptide, "the proline moiety of which exists in its dextrorotatory optical isomer form (DPro)." See, for example, Table 1 of Hiltz at page 768, 3rd listed peptide. Hiltz further describes a test protocol for evaluating the anti-inflammatory activity of peptides, including lysine-D (dextrorotatory) proline-valine tripeptide. According to that protocol, the tripeptide is administered to female BALB/C mice at doses of 10 μ g (2.6×10^{-8} M), 20 μ g (5.2×10^{-8} M), 40 μ g (1.04×10^{-7} M) and 80 μ g (2.08×10^{-7} M) in 0.2 ml of sterile saline. See Hiltz, paragraph bridging pages 768 and 769. Those amounts would appear no different from the "anti-inflammatory effective amount" recited in claim 1 on appeal, which "reads on" a concentration ranging from 10^{-12} M to 10^{-3} M, preferably from 10^{-9} M to 10^{-4} M (Specification, page 6, lines 14 through 21). In other words, as best we can judge, Hiltz describes administering the same active agent in the same effective amount recited in claim 1 on appeal.

The next question is whether Hiltz describes "a method of treating inflammation" by administering an anti-inflammatory effective amount of lysine-Dproline-valine, in 0.2 ml of sterile saline, to laboratory mice. We would answer that question in the affirmative, based on a fair evaluation of the Hiltz reference in its entirety. In this regard,

² Hiltz et al. (Hiltz), "Anti-Inflammatory Activity of α -MSH(11-13) Analogs: Influences of Alteration in Stereochemistry," Peptides, Vol. 12, pp 767-771, (1991).

we invite attention to Table 1 of Hiltz at page 768, 3rd listed peptide. There, in numerical terms, Hiltz describes the anti-inflammatory activity of the lysine-Dproline-valine tripeptide.³

For these reasons, it would not appear that there is any limitation in claim 1 serving to distinguish applicants' method from the method described by Hiltz. On return of this application, in light of the foregoing remarks, we recommend that the examiner engage in a claim by claim analysis and reevaluate the patentability of all the appealed claims over Hiltz.

Applicants characterize Hiltz as teaching that:

when the proline residue exists in the tripeptide [lysine-proline-valine] in its dextrorotatory optical isomer form (Dpro), the tripeptide ... lost all effectiveness in the treatment of inflammation (Hiltz et al., Peptide, Vol. 12, pp. 767-771 (1991)). [Specification, page 3, lines 13 through 18, emphasis added]

We disagree with that characterization which, we believe, is contradicted by the data in Table 1 of Hiltz.

Nor have we overlooked passages in Hiltz stating that (1) the lysine-proline-valine tripeptide, where proline exists in its dextrorotatory optical isomer form (DPro), has no "significant" anti-inflammatory activity; and (2) two peptides with dextro-valine conformations induce more consistent, large anti-inflammatory effects compared with the lysine-proline-valine tripeptide, where proline exists in its dextrorotatory form (DPro). See Hiltz, page 770, column 1, first full paragraph; and page 770, paragraph bridging columns 1 and 2. The fair inference of those passages, we believe, is that applicants'

³ The methodology or test protocol of Hiltz is described in a section entitled "METHOD" on pages 768 and 769. Hiltz treats laboratory mice with picryl chloride to induce ear swelling, and the data in Table 1 is expressed as percent inhibition of swelling.

tripeptide possesses some anti-inflammatory activity, a fact best illustrated by the data in Table 1, page 768.

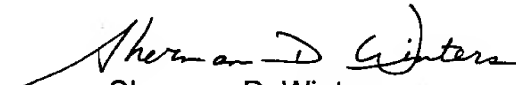
To the extent applicants would argue that Hiltz teaches unsatisfactory results, whereas they show successful results using the same tripeptide, we invite attention to Celeritas Technologies Ltd. v. Rockwell International Corp., 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522 (Fed. Cir. 1998) (A reference is no less anticipatory if, after disclosing the invention, the reference then disparages it. Thus, the question whether a reference "teaches away" from the invention is inapplicable to an anticipation analysis). Applicants and the examiner should also consider In re Woodruff, 919 F.2d 1575, 1578 16 USPQ2d 1934, 1936 (Fed. Cir. 1990) (It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable); and Ex parte Thumm, 132 USPQ 66, 67-68 (Bd. App. 1960) (if applicant's claims read directly on what is disclosed in the prior art, such claims cannot be allowed even though the prior art teaches unsatisfactory results whereas the applicant demonstrates successful results. It is elementary that the applicant's claims must define something specifically different from what is explicitly taught by the prior art and the change must not be an obvious one).

CONCLUSION

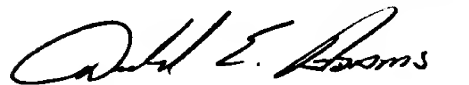
In conclusion, for the reasons set forth in the body of this opinion, we reverse the examiner's rejections under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a). On return of this application to the examining corps, we recommend that the examiner reevaluate whether claim 3 constitutes a proper dependent claim. We also recommend that the examiner reevaluate the patentability of all the appealed claims over Hiltz.

The examiner's decision is reversed.

REVERSED


Sherman D. Winters
Administrative Patent Judge


Toni R. Scheiner
Administrative Patent Judge


Donald E. Adams
Administrative Patent Judge

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